BioInvent announces the enrollment of the first patient in triple combination arm of BI-1206, rituximab and Calquence® for the treatment of non-Hodgkin's lymphoma

- First patient enrolled in Phase 2a study arm combining BI-1206 with rituximab and acalabrutinib with initial data expected YE 2024
- Clinical supply agreement for acalabrutinib with AstraZeneca in place

Lund, Sweden – September 12, 2024 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces it has enrolled the first patient in the triple combination arm of the Phase 1/2a study of its anti-FcgRIIB antibody, BI-1206 in non-Hodgkin's lymphoma (NHL).

The Phase 2a study arm will combine the subcutaneous formulation of BI-1206 and rituximab with Calquence® (acalabrutinib), a selective inhibitor of Bruton's tyrosine kinase (BTK). Approximately 30 patients are expected to be enrolled in Spain, Germany, the US, and Brazil. Preliminary data are expected by the end of 2024. In February 2024 BioInvent signed a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) to provide Calquence® for the combination arm.

"The enrolment of the first patient in the study is an important milestone as we move forward to evaluate this triple combination as a potential new treatment option for patients with non-Hodgkin's lymphoma," said **Martin Welschof, Chief Executive Officer of BioInvent**. "The combination of BI-1206 and rituximab has already demonstrated promising signs of clinical efficacy with a favorable safety profile, and we have strong reasons to believe that the addition of acalabrutinib will increase response rates even further; the subcutaneous formulation of BI-1206 is expected to provide a great deal of flexibility and further improve the tolerability of the treatment."

About BI-1206
BI-1206 is one of BioInvent's most advanced drug candidates and is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab, drugs with combined global sales of approximately USD 23 billion annually.

The drug candidate is evaluated in two separate clinical programs, one for the treatment of non-Hodgkin's lymphoma (NHL, a type of blood cancer) and one for the treatment of solid tumors. Two delivery formulations (intravenous (IV) and subcutaneous (SC)) of BI-1206 are being evaluated in parallel.

BI-1206 in NHL
All patients in the ongoing Phase 1/2a study (NCT03571568) have previously been treated with one or more rituximab containing treatments. Latest results were presented in connection with EHA (European Hematology Association) congress in June 2024: the intravenous (IV) Phase 1 part (dose escalation) showcased responses across the dose range of 30-100 mg, including 5 patients with complete response (CR), 1 with partial response (PR) and 6 patients with stable disease (SD) out of 17 evaluable patients. First data from the subcutaneous (SC) Phase 1 part (dose escalation) showed 1 CR, 2 PR and 1 SD out of 4 evaluable patients.

About BioInvent
BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical-stage biotech company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with currently five drug candidates in six ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors. The Company's validated, proprietary F.I.R.S.T™ technology platform identifies both targets and the antibodies that bind to them, generating many promising new immune-modulatory candidates to fuel the Company's own clinical development pipeline and providing licensing and partnering opportunities.

The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit. More information is available at www.bioinvent.com. Follow us on the social media platform X: @BioInvent.

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Attachments

BioInvent announces the enrollment of the first patient in triple combination arm of BI-1206, rituximab and Calquence® for the treatment of non-Hodgkin's lymphoma